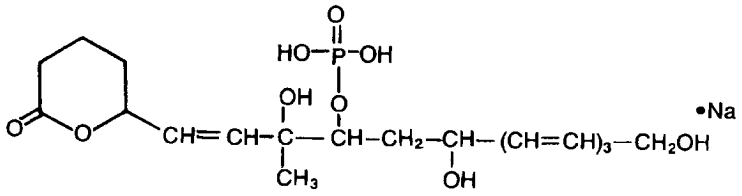
FOSTRIECIN SODIUM

NSC - 339638



Chemical Name: 5,6-dihydro-6-[3,6,13-trihydroxy-3-methyl-4-(phosphonooxy)-1,7,9,11-tridecatetraenyl]-2H-Pyran-2-one, monosodium salt

Other Names: Pyranone Phosphate; Phosphotrienin, Fostriecin Sodium (USAN)

CAS Registry Number: 87810-56-8

Molecular Formula: $C_{19}H_{26}O_9$ P . Na **M.W.**: 452.4

How Supplied: For Injection, 25 mg, prepared as an off white or pale yellow lyophilized powder with 39 mg of ascorbic acid and sodium hydroxide to adjust pH.

Solution Preparation: 25 mg/vial: When constituted with 2 mL of 0.9% Sodium Chloride Injection, USP, each millimeter contains 12.5 mg of Fostriecin and 19.5 mg of ascorbic acid with sodium hydroxide to adjust to pH 6.5 to 7.5.

Storage: The intact vials should be stored in the freezer (-10 to -20°C) and protected from light.

Stability: Shelf-life surveillance of the intact vials is ongoing.

Fostriecin exhibits maximum stability in aqueous solution in the pH range of 6.5 to 7.5. When constituted as directed, the solution exhibits no detectable decomposition in eight hours and about 4% loss in 24 hours at room temperature. Approximately 20 to 25% loss occurs after seven days of room temperature storage. When stored under refrigeration, less than 5% loss occurs in seven days.

> **CAUTION:** This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

When diluted to a concentration of 0.05 mg/mL in 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, for intravenous infusion, about 2 to 4% loss occurs in 24 hours at room temperature. The infusion solutions were stable for four days when stored under refrigeration at 4 °C exhibiting little or no loss.

The Fostriecin solutions were substantially less stable when stored frozen at -20°C compared to room temperature or refrigerator storage. Consequently, storage of frozen solutions of Fostriecin is not recommended. However, frozen storage of the intact vials with the drug in the dry state is required to maximize long-term stability.

Route of Administration: Intravenous